Health Alliance™

Pharmacy Drug Policy & Procedure

Policy Name:	Hepatitis B Treatment	Policy#:	936P

Purpose of the Policy

The purpose of this policy is to establish guidelines for coverage of medications in the treatment of chronic Hepatitis B infection.

Statement of the Policy

Health Alliance Medical Plans will approve the use of chronic Hepatitis B treatments, including Hepsera (adefovir), Baraclude (entecavir), Pegasys (peginterferon alfa-2a), and Vemlidy (tenofovir alafenamide) when the following criteria have been met.

Criteria

1. Hepatitis B Coverage Criteria

1.1 Documentation of hepatitis B with one of the following:
- Without cirrhosis:
  - HBeAg+, HBV >20,000IU/mL, ALT> 2x ULN OR
  - HBeAg-, HBV >2000 IU/mL, and histological disease such as necroinflammation, significant fibrosis
- With cirrhosis:
  - HBV >2000 OR
  - Decompensated disease

2. Hepatitis B Prophylaxis Criteria

2.1 Documented HBV infection prophylaxis (preventative therapy) with liver transplant

3. Exclusion Criteria

3.1 Hepsera
- Children under age 12 – Safety and efficacy have not been established for this population

3.2 Pegasys (peginterferon alfa-2a)
- Contraindicated in decompensated liver disease
- Patients under 3 years old

3.3 Vemlidy for patients under 6 years old or <25kg

3.4 Baraclude for patients under 2 years old

4. Approval Period

4.1 Initial Approval: 1 year

4.2 Reapproval: 1 year with documented benefit to therapy including a decrease in HBV DNA levels or ALT or AST (liver function enzymes)
- Note: treatment duration of nucleoside analog-based therapy is variable and influenced by HbeAg status, duration of HBV suppression, and presence of cirrhosis/decompensation (AASLD practice guidelines).

CPT Codes

HCPCS Codes	

References

1. Lai C, Shouval D, Lok A, et al. Entecavir versus Lamivudine for Patients with HbeAg-Negative Chronic Hepatitis B, The New England Journal of Medicine, 9 March 2006, v354:1011–1020.
2. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. Hepatology. 2018 Apr;67(4):1560-1599.

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DISCLAIMER
This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies.
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